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EXAMINER	
NGUYEN, TRAN N	
ART UNIT	**PAPER NUMBER**
2197	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/849,020	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	Tran N. Nguyen	2197	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 May 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner has conducted a complete, thorough, and best-effort examination even though **the application is replete with errors.** Examiner respectfully requests and strongly urges Applicant to review the application in its entirety in view of the issues raised herein.

Priority

Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in Germany on May 20, 2003. It is noted, however, that **Applicant has not filed a certified English translation** of the **DE 103 22 683.4** application as required by 35 U.S.C. 119(b). Correction is required.

Examiner respectfully reminds Applicant that **such English translation should be filed together with a statement that the translation of the certified copy is accurate**. This is necessary to ensure that no new matter is introduced in translation.

Drawings

The drawings are objected to because they are replete with errors. Examiner respectfully requests and strongly urges Applicant to review all drawings in their entirety. Objections to the drawings include, but are not limited to the following:

- The unlabeled rectangular boxes shown in all figures should be provided with **descriptive text labels**.
- The same structural entity is being assigned different terminology throughout the application. Examples of this error include, but are not limited to:
    - Data record DS and therapeutic information item 1 [0030].
    - Medical treatment 2n and data item D [0031].
- Examiner requires Applicant to amend the drawings to properly show the data structure of the therapeutic information items as they relate to data records.
- Referencing should be illustrated by means of pointers linking the inputs and outputs of the therapeutic information item to other therapeutic information and data items.
- Deep and shallow copying should be **clearly inferable** from the drawings.
- Recursive structures should be illustrated as such.
- **Proper numbering** of elements and sub-elements (e.g. element A containing a plurality of sub-elements A_1, A_2, ..., A_i) should be employed.
- Different instantiations of the structure used to illustrate genus and species variations of the structure should be **properly labeled with non-conflicting numbers and terminology** as to avoid confusion.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by Examiner, Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Abstract

The abstract is objected to because it is replete with errors. Examiner respectfully requests and strongly urges Applicant to review the abstract in its entirety in view of the issues raised herein. Objections to the abstract include, but are not limited to the following:

- It is not possible to ascertain the scope of the technical disclosure from the contents of the abstract. The abstract **should include the**

major steps of the process as described in the technical disclosure. The abstract in current form does not concisely describe the invention.

- "The method further includes using **the identified at least one periodicity criterion** to ascertain a subsequent treatment." Examiner suggests Applicant to revise for clarity.

Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

(1) if a machine or apparatus, its organization and operation;

(2) if an article, its method of making;

(3) if a chemical compound, its identity and use;

(4) if a mixture, its ingredients;

(5) **if a process, the steps**.

Extensive mechanical and design details of apparatus should not be given.

Applicant is also reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. **The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.**

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be

implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specification

A **substitute specification in proper idiomatic English** and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of

some unclear, inexact or verbose terms used in the specification include, but are not limited to:

The term "data record", first appearing in paragraph [0002] and referred to throughout the application, is ambiguous. Since Applicant's explicit definition in is ambiguous, it is especially unclear if a "data record" refers to a single element of a collection of information (a row in a table), as is standard in database terminology, or the complete collection of all data about a patient as comprising that patient's medical record, as is standard in medical terminology.

The term "therapeutic information item" is given numerous different and conflicting throughout the application.

Additional errors exist in the disclosure. **Examiner requires Applicant to address these inconsistencies as they preclude a thorough examination of the instant pending application**.

For examination purposes, the following assumptions have been made in a best-effort attempt to comprehend Applicant's disclosure:

- The term "data record" has been given its **ordinary meaning in the medical industry**.
- A "therapeutic information item" is interpreted to mean **patient data**.

- The "periodicity criterion" is interpreted to mean recurring treatment.

The disclosure is objected to because of the following informalities:

- "The invention generally relates to a method for processing periodically recurring or consecutive treatments for a patient using a data record **which** includes therapeutic information items" [0002]. It is unclear to what the qualifier "which" refers.
- "...the widespread use of therapeutic information items (= patient data items)..." [0006]. Examiner respectfully suggests Applicant to not employ the use of the equal sign "=".
- "... on a **person** computer used by a doctor..." [0044]. Examiner respectfully suggests Applicant to revise the word "person" to "personal".
- "**The or each** input E..." [0046]. Examiner respectfully suggests Applicant to revise for clarity.
- Examiner respectfully requests Applicant to number the lines on each page (including the abstract), in addition to the existing paragraph numbering, to facilitate the examination process.

Additional errors exist in the disclosure. Appropriate correction is required.

Claim Objections

Claims 15, 16, and 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

With respect to claim 15, it is inherent that any electronic patient data is contained in memory. Claim 15's recitation of such storage in memory does not further limit the parent claim.

With respect to claim 16, the term "basic data items" are ambiguous and does not further limit the parent claim.

With respect to claim 21, Applicant's recitation of "an institute which collects the examination results" is given no limiting effect on the scope of the claim because this recitation is an intended use of the reporting feature.

Applicant is advised that should claims 1, 18, 19, 28, and 29 be found allowable, claims 25, 26, 27, 30, and 31, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 28-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The language of the claims raise a question as whether the claims are directed merely to an abstract idea that is not a statutory category of invention (process, machine, manufacture or composition of matter) which would result in a practical application, producing a concrete, useful, and tangible result.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **It is not clear to one of ordinary skill in the art how to use a treatment to output a report**.

Examiner suggests Applicant to revise the wording of the rejected claims to recite the incorporation of data contained in the treatment into a report.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. All pending claims are replete with errors. Again, Examiner respectfully urges Applicant to consider the **use of proper idiomatic English**. Applicant's attention is directed to instances when **word choice, sentence structure, and punctuation render the claim indefinite**. It is therefore **not possible to fully ascertain Applicant's claimed invention from Applicant's claim recitation**.

With respect to independent claim 1, examples where claim 1 fails to particularly point out and distinctly claim the invention include, but are not limited to, the following:

- The functionality of a therapeutic information item.
- The functionality of a data record.
- The steps involved in the method.

All claims dependent thereon fail to remedy these deficiencies, and are also rendered indefinite.

Independent claims 25, 32, and all claims dependent thereon are also rejected under the same rationale.

With respect to claim 4, the term "respective" is unclear because it is ambiguous which entity is providing perspective. For examination purposes, claim 4 is interpreted to recite the use of periodicity criterion to ascertain the next treatment for multiple concurrent treatments.

With respect to claim 5, the term "subsequent" is unclear because it is unclear which entity is providing perspective. For examination purposes, claim 5 is interpreted to recite the determination of the next treatment for a given treatment.

With respect to claim 6, the term "said treatment" is ambiguous because multiple treatments exist in the scope of claim 6 and parent claim 1. For examination purposes, claim 6 is interpreted to recite the identification of duplicate treatments.

With respect to claim 7, the wording renders the claim ambiguous. For examination purposes, claim 7 is interpreted to recite the exercising of discretionary measures when duplicate treatments are identified to prevent duplication of services and reduce cost, according to Applicant's disclosure [0005].

With respect to claim 13, the term "user" is ambiguous. It is unclear how a user would use a treatment. For examination purposes, claim 13 is interpreted to recite the assignment of treatment to a patient.

With respect to claim 14, the destination where a treatment is forwarded is ambiguous. Claim 14 is interpreted to recite that a treatment is available for viewing.

With respect to claim 16, the term "basic data items" is ambiguous. No reasonable interpretation can be ascertained from claim 16. Therefore, claim 16 cannot be examined at this time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-32 are rejected under 35 U.S.C. 102(b) as being unpatentable under U.S. Patent 5,737,539 issued to Edelson et al. (hereafter referred to as Edelson '539).

With respect to claim 1, the structural limitation present in the preamble and throughout the claim is given no limiting effect on the method steps. For examination purposes, claim 1 is interpreted to recite a method comprising of the steps of identifying a periodicity criterion, and ascertaining a subsequent treatment.

With respect to claims 1, 18, 19, 25, 26, and 27 Edelson '539 teaches a "system [that] knows dosage, dosage frequency and the duration of all prescriptions." As such, "it [the system] can report out what pills should be taken at different times of the day to comply with the requirements of multiple medications. The information used for such a further report can drive the dispensing of the drugs of a multi-drug prescription..." (column 28, lines 13-16).

According to Edelson '539, the system identifies at least one periodicity criterion, i.e. dosage frequency and duration, and uses that criterion to ascertain a subsequent treatment, i.e. drive the dispensing of drugs.

With respect to claim 2, Edelson '539 further teaches that new patient records may be posted (column 14, lines 23-60 and Figure 2) and be assigned a drug with a dosing frequency (column 25, lines 58-63 and Figure 3). Therefore, as new therapeutic information items, i.e. records, are added, at least one periodicity criterion is identified.

With respect to claim 3, Edelson '539 further teaches "a scheduled dosage drug pack 182 configured as a daily pack with the day of the week prominent and

the date, patient and doctor identified" (column 28, lines 21-23 and Figure 15). Therefore, the periodicity criterion is used to ascertain an associated time of execution for the subsequent treatment, i.e. the next time the drug is to be administered to the patient.

With respect to claim 4, Edelson '539 further teaches "that by giving the physician-prescriber some physical control over the circumstances that exist when a patient is supplied with drug therapy for remote administration, the prescriber gains the freedom to adopt **time-related dosage variations** during the course of therapy" (column 29, lines 1-6).

With respect to claim 5, Edelson '539 further teaches "regimens [that] could provide higher initial dosages to build up blood drug levels, followed by lower maintenance dosages" (column 29, lines 10-12). Therefore, a previous treatment determines the subsequent treatment.

With respect to claims 6 and 7, Edelson '539 further teaches that "a physician, or perhaps pharmacist... sees a similar current prior prescription has been issued, they [the physician or pharmacist] can refuse to duplicate it [the new prescription]" (column 27, lines 40-43).

With respect to claims 8-10, and 21, Edelson '539 further teaches that "it [the system] can report out what pills should be taken at different times of the day

to comply with the requirements of multiple medications. The information used for such a further report can drive the dispensing of the drugs of a multi-drug prescription..." (column 28, lines 13-16).

With respect to claims 11-12, Edelson '539 further teaches "an ability to compile what may be termed a "virtual" patient record from multiple remote databases of primary source information" (column 8, lines 21-24). Therefore, according to Edelson '549's teachings, patient data may be stored centrally at remote databases, and individual records may be assembled on a local computer and stored thereon temporarily.

With respect to claims 13, Edelson '539 further teaches the assigning of prescription drugs to patients (Figure 3).

With respect to claims 14, 20, and 24, Edelson '539 further teaches "tracking means to track preferred data usage by a user and to adapt data displays to favor such preferred usage, whereby the system learns and adapts to a user's habits" (column 5, lines 14-16). Therefore, a patient who is on a treatment may view the data display to ascertain the next subsequent treatment.

With respect to claims 15-17, Edelson '539 teaches that the system further comprises of a dosage for a prescribed drug (column 4, line 34). A prescription

drug dosage inherently contains a start time, an end time, and a periodicity criterion.

With respect to claim 22, Edelson '539 further teaches "continuous post-market-introduction monitoring of a drug in relation to the treatment of conditions is possible, and an end-to-end solution to the problem of managing unanticipated problems arising with new drugs can be provided: the system provides a vehicle data collecting relevant data; parameters and a means for analysis of that data; and a means for disseminating alerts and advisories regarding newly discovered problems" (column 23, lines 26-33). Therefore, according to the teachings of Edelson '539, relevant patient data may be collected and compared with established parameters. It is inherent that data comparison may be either qualitative or quantitative. Quantitative data comparison may be greater than or less than an established parameter value.

With respect to claim 23, Edelson '539 further teaches "a scheduled dosage drug pack 182 configured as a daily pack with the day of the week prominent and the date, patient and doctor identified" (column 28, lines 21-23 and Figure 1). Therefore, each treatment is assigned to at least one doctor.

With respect to claims 28-31, Edelson '539 further teaches "software components and applications embodying the invention [that] can be distributed in electronic bit storage" (column 52, lines 66-67, and column 53, lines 1-5).

With respect to claim 32, the limitation of claim 1 substantially encompasses the limitation of claim 32; i.e. they are of substantially the same scope. Therefore, claim 32 is rejected for at least the same reasons as claim 1.

Conclusion

Applicant's cited references have been considered; however, portions of foreign references not in English have not been considered. Only the English abstract of such references, if available, have been considered.

Even if the claims were amended to an allowable state, the specification, drawings, and abstract are replete with errors, and would prevent timely and favorable action for Applicant. Therefore, **Examiner respectfully requests and strongly urges Applicant to reconsider the application in its entirety.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran N. Nguyen whose telephone number is (571) 270-1310. The examiner can normally be reached on Monday - Friday, 7:0 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 274-1279. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tran N Nguyen
Examiner
Art Unit 2197

TN
9/26/2006

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